

## CLAIMS

What is claimed is:

1. A method for treating a lower urinary tract disorder characterized by  
5 having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia, which comprises administering to an individual in need thereof a therapeutically effective amount of a first component that is an  $\alpha_2\delta$  subunit calcium channel modulator, in combination with a second component that is a smooth muscle modulator.
- 10 2. The method of claim 1, wherein said first component and said second component are contained within a single pharmaceutical formulation.
3. The method of claim 1, wherein said first component and said second  
15 component are contained within separate pharmaceutical formulations.
4. The method of claim 3, wherein said first component and said second component are administered concurrently.
- 20 5. The method of claim 3, wherein said first component and said second component are administered sequentially.
6. The method of claim 1, wherein the  $\alpha_2\delta$  subunit calcium channel modulator is a GABA analog.
- 25 7. The method of claim 6, wherein the GABA analog is Gabapentin or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

8. The method of claim 6, wherein the GABA analog is Pregabalin or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

5 9. The method of claim 1, wherein said smooth muscle modulator is selected from the group consisting of: antimuscarinics,  $\beta_3$  adrenergic agonists, spasmolytics, neurokinin receptor antagonists, bradykinin receptor antagonists, and nitric oxide donors.

10 10. The method of claim 9, wherein said smooth muscle modulator is an antimuscarinic.

11. The method of claim 10, wherein the antimuscarinic is Oxybutynin or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

15 12. The method of claim 10, wherein the antimuscarinic is Tolterodine or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

20 13. The method of claim 10, wherein the antimuscarinic is Propiverine or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

25 14. The method of claim 10, wherein the antimuscarinic is Solifenacin monohydrochloride or an acid, salt, enantiomer, analog, ester, amide, prodrug, active metabolite, or derivative thereof.

30 15. The method of claim 1, wherein said  $\alpha_2\delta$  subunit calcium channel modulator is Gabapentin or acids, salts, enantiomers, analogs, esters, amides, prodrugs, active metabolites, and derivatives thereof, and wherein said smooth muscle modulator is

Oxybutynin or acids, salts, enantiomers, analogs, esters, amides, prodrugs, active metabolites, and derivatives thereof.

16. The method of claim 1, wherein said  $\alpha_2\delta$  subunit calcium channel  
5 modulator is Pregabalin or acids, salts, enantiomers, analogs, esters, amides, prodrugs, active metabolites, and derivatives thereof, and wherein said smooth muscle modulator is Oxybutynin or acids, salts, enantiomers, analogs, esters, amides, prodrugs, active metabolites, and derivatives thereof.

10 17. The method of claim 1, wherein said first component and said second component are administered on an as-needed basis.

18. The method of claim 1, wherein said first component and said second  
15 component are administered prior to commencement of an activity wherein suppression of the symptoms of a lower urinary tract disorder would be desirable.

19. The method of claim 18, wherein said first component and said second  
component are administered from about 0 to about 3 hours prior to commencement of an  
activity wherein suppression of said symptoms would be desirable.

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20. The method of claim 1, wherein said first component and said second  
component are administered orally, transmucosally, sublingually, buccally, intranasally,  
transurethrally, rectally, by inhalation, topically, transdermally, parenterally,  
intrathecally, vaginally, or perivaginally.

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21. The method of claim 1, wherein said first component and said second  
component are administered to treat overactive bladder or the irritative or obstructive  
symptoms of benign prostatic hyperplasia.

30 22. The method of claim 1, wherein said first component and said second component are administered to treat urinary frequency.

23. The method of claim 1, wherein said first component and said second component are administered to treat urinary urgency.

5           24. The method of claim 1, wherein said first component and said second component are administered to treat nocturia.

25. The method of claim 1, wherein at least one detrimental side effect associated with single administration of said first component or single administration of  
10 said second component is lessened by concurrent administration of said first component and said second component.

26. The method of claim 25 wherein said first component and said second component are administered to treat overactive bladder or the irritative or obstructive  
15 symptoms of benign prostatic hyperplasia.

27. A method for treating a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia, comprising administering to an individual in need thereof  
20 a therapeutically effective amount of at least one component selected from an  $\alpha_2\delta$  subunit calcium channel modulator and a smooth muscle modulator.

28. A pharmaceutical composition comprising a first component that is an  $\alpha_2\delta$  subunit calcium channel modulator, in combination with a second component that is a  
25 smooth muscle modulator, wherein said first component and said second component are in amounts sufficient to treat a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia.

30           29. A pharmaceutical composition comprising a first component that is Gabapentin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or

active metabolites thereof, in combination with a second component that is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, wherein said first component and said second component are in amounts sufficient to treat a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia.

30. The pharmaceutical composition of claim 29 wherein said first component is present in an amount from about 50 mg to about 2400 mg, and wherein said second component is present in an amount equal to or less than about 5 mg.

31. The pharmaceutical composition of claim 30 wherein said first component is in an amount of about 200 mg.

32. The pharmaceutical composition of claim 30 wherein said second component is in an amount of about 2.5 mg.

33. The pharmaceutical composition of claim 30 wherein said second component is in an amount of about 1.25 mg.

34. A pharmaceutical composition comprising a first component that is Pregabalin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, in combination with a second component that is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, wherein said first component and said second component are in amounts sufficient to treat a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia.

35. A pharmaceutical composition for the treatment of a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting

of urinary frequency, urinary urgency, and nocturia, comprising a first component that is Gabapentin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, in combination with a second component that is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, wherein said first component and said second component are present in a ratio from about 1:1 to about 800:1 or from about 1:1 to about 1:800, respectively, based on a fraction of their respective ED<sub>50</sub> values.

36. A combination for the treatment of a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia, comprising a first component that is Gabapentin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, in combination with a second component that is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, wherein said first component and said second component are in a weight/weight ratio of from 1:1 to about 800:1 or from about 1:1 to about 1:800, respectively.

37. A pharmaceutical composition comprising Oxybutynin, wherein said Oxybutynin is in an amount less than about 2.5 mg.

38. A packaged kit for a patient to use in the treatment of a lower urinary tract disorder characterized by having at least one symptom selected from the group consisting of urinary frequency, urinary urgency, and nocturia, comprising: at least one component selected from an  $\alpha_2\delta$  subunit calcium channel modulator and a smooth muscle modulator; a container housing said component or components during storage and prior to administration; and instructions for carrying out drug administration of an  $\alpha_2\delta$  subunit calcium channel modulator with a smooth muscle modulator in a manner effective to treat said lower urinary tract disorder.

39. The packaged kit of claim 38 wherein said first component and said second component are contained in the same pharmaceutical formulation.

40. The packaged kit of claim 39 wherein said first component is Gabapentin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, and wherein said second component is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof.

41. The packaged kit of claim 38 wherein said first component and said second component are contained in separate pharmaceutical formulations.

42. The packaged kit of claim 41 wherein said instructions include directions for carrying out drug administration of said first component and said second component sequentially or concurrently.

43. The packaged kit of claim 42 wherein said first component is Gabapentin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof, and wherein said second component is Oxybutynin or pharmaceutically acceptable acids, salts, esters, amides, prodrugs, or active metabolites thereof.

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